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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
ERIC A. JOHNSON, HUEI-HSIUNG YANG,
BERIL GELDIAY-TUNCER, WILLIAM T.
HALL, DAVID SCHREIBER, and
KWOK HO

Application No. 08/458,019

Filed: June 1, 1995

For: PROCESSES FOR IN VIVO
PRODUCTION OF ASTAXANTHIN
AND PHAFFIA RHODOZYMA
YEAST OF ENHANCED
ASTAXANTHIN CONTENT

Attn: Office of the Solicitor

Appeal No. 2002-1297

Examiner: H. Lilling

**NOTICE OF APPEAL TO THE UNITED STATES COURT OF APPEALS FOR THE
FEDERAL CIRCUIT**

Pursuant to 35 U.S.C. §§ 141 and 142, IGENE Biotechnology, Inc. ("IGENE") hereby appeals to the United States Court of Appeals for the Federal Circuit from the Decision of the Board of Patent Appeals and Interferences in Appeal No. 2002-1297 that was mailed on January 30, 2004, and docketed on February 2, 2004. Appellant IGENE is the owner of the entire right and interest of Application No. 08/458,019 by virtue of an Assignment from all of the inventors recorded at Reel 4952, Frame 0724.

Pursuant to Federal Rules of Appellate Procedure Rule 15(a)(2)(B), IGENE names the United States Patent and Trademark Office as an appellee. A copy of the Decision of the Board


of Patent Appeals and Interferences from which IGENE hereby appeals is attached to this Notice of Appeal.

Dated: March 29, 2004

Respectfully submitted,

GRAY CARY WARE & FREIDENRICH LLP

By


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MAR 29 2004

U.S. PATENT & TRADEMARK OFFICE

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Appln. No. 08/458,019

Filed: June 1, 1995

For: PROCESSES FOR IN VIVO
PRODUCTION OF
ASTAXANTHIN AND PHAFFIA
RHODOZYMA YEAST OF
ENHANCED ASTAXANTHIN
CONTENT

Group Art Unit: 1651

Examiner: H. Lilling

Atty. Docket No. 2502495-991100
(Old No. A62741)

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PATENT TRADEMARK OFFICE

PAPER(S) FILED ENTITLED:

1. Submission of Revocation and Power of Attorney
2. Notice of Appeal to the United States Court of Appeals
for the Federal Circuit
(w/copy of Decision on Appeal as mailed on Jan. 30,
2004)

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The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 43

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UNITED STATES PATENT AND TRADEMARK OFFICE

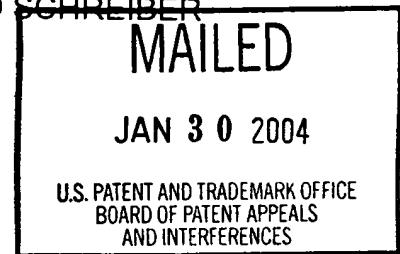
**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

FEB 2 2004

Ex parte ERIC A. JOHNSON, HUEI-HSIUNG YANG,
BERIL GELDIAY-TUNCER, WILLIAM T. HALL, DAVID SCHREIBER
and KWOK HO

Appeal No. 2002-1297
Application No. 08/458,019

ON BRIEF



3/30

Before WINTERS, SCHEINER and MILLS, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the final rejection of claims 25-34, all the claims remaining in the application.

Claims 25, 29, 30 and 34 are representative of the subject matter on appeal and read as follows:

25. An astaxanthin mutant *Phaffia rhodozyma* producing more astaxanthin than naturally occurring *Phaffia rhodozyma*, said mutant producing more than 700 micrograms of astaxanthin per gram of dry yeast per six-day culture in YM medium, wherein the amount of astaxanthin is determined by measuring the absorbance at 474 nanometers of a petroleum ether extract of *Phaffia rhodozyma* using a 1% (w/v) extinction coefficient in a one centimeter cuvette of 2100.

29. The mutant yeast of claim 28, wherein said mutant yeast produces more than 1700 µg of astaxanthin per gram of dry yeast.

30. The mutant yeast of claim 25, wherein said mutant yeast produces astaxanthin at a level at least two times that of naturally occurring *Phaffia rhodozyma*.

34. The mutant yeast of claim 33, wherein said mutant yeast produces astaxanthin at a level at least six times that of naturally occurring *Phaffia rhodozyma*.

The sole reference relied on by the examiner is:

Flenø et al. (Flenø)	5,356,810	Oct. 18, 1994
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Claims 25-34 stand rejected under the first paragraph of 35 U.S.C. § 112 "for lack of the requested required deposits commensurate in scope with the claimed inventions," "for the written description requirement," and "with respect to the [requirement for an] enabling description" (Answer, page 3). In addition, claims 25-34 stand rejected under the doctrine of obviousness-type double patenting as unpatentable over the sole claim of U.S. Patent No. 5,356,810 to Flenø.

On consideration of the record, we affirm the rejection of claims 25-34 on the grounds of obviousness-type double patenting, but reverse the rejections of the claims under the first paragraph of 35 U.S.C. § 112.

DISCUSSION

35 U.S.C. § 112, 1st ¶

The present claims are broadly drawn to mutant strains of *Phaffia rhodozyma* capable of producing various minimum levels of astaxanthin. On pages 13-27 of the Answer, the examiner sets forth three separate rejections under 35 U.S.C. § 112, first paragraph, one based on the requirement for an adequate written description, one based on the requirement for an enabling disclosure, and one based on the

requirement for the deposit of certain microorganisms in a recognized depository. Each of the rejections appears to be predicated on a recurrent theme or themes, so we will discuss them together.

According to the examiner, “[a]ppellants have already been granted claims as broad as the written disclosure based on the [] strains [deposited]” (Answer, page 18) in connection with “the claims allowed . . . in U.S. Patent Number 5,356,809” (id., page 13). To the extent we understand the examiner’s position, it is that the present generic claims are broader than those allowed in related U.S. Patent 5,536,809 (see, e.g., pages 13 and 15); that all of the mutant strains of Phaffia rhodozyma specifically described in the present specification (as well as the numerous strains described in the November 7, 1997 declaration of Dr. Stephen Hiu) were obtained by a selection protocol involving “(a) antibiotic, (b) cytochrome B inhibitor or (c) terpenoid synthetic pathway inhibitor” (see id., pages 15, 18 and 22), but the claims would read on “strains prepared by another and materially different method” (see id., pages 13 and 17); that “naming a type of material generally known to exist . . . is not a description of that material” (id., page 22); and finally, that appellants are only enabled for mutants “obtained by the methods as described . . . without undue experimentation” (id., pages 22-23) because of the “unpredictability pertaining to microorganisms [which] is supported by the U.S. Rules of Deposits which requires deposits of new microorganisms in Depositories” (id., page 23).

We cannot agree with the examiner’s position in any of these rejections. While there is a certain degree of unpredictability associated with both mutation and selection, the specification need only teach one skilled in the art to make and use the claimed

invention without undue experimentation. "The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation 'must not be unduly extensive.'" PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996) (citations omitted). The claims at issue are directed to Phaffia rhodozyma mutants producing various minimum levels of astaxanthin, and the examiner does not dispute that appellants have provided ample evidence that mutants meeting the limitations of the claims can be reliably obtained according to the protocol described in the specification. The examiner has not explained why appellants should be required to teach more than one protocol for obtaining the various mutants encompassed by the claims. The examiner's concern that the claims may read on mutants obtained by other methods would seem to be more relevant to an analysis of the claims with respect to prior art.

Nor is it clear what the examiner would have appellants deposit. The present claims are generic in nature; none is drawn to a particular strain. What would satisfy the examiner's requirement for deposit of "a reasonable number of species that would be commensurate in scope with the term 'mutant'?" Moreover, the examiner has not provided a fact-based explanation as to why it would be appropriate to require a deposit to enable or describe mutants meeting the requirements of the claims in the first place, inasmuch as it has not been established that the starting materials (cultures of naturally occurring Phaffia rhodozyma) would have been unavailable to the public. Finally, while we might agree with the examiner that "naming a type of material generally known to exist . . . is not a description of that material" (Answer, page 22), that is hardly the case here. Appellants have described numerous examples of Phaffia rhodozyma mutants with the required functional properties.

Obviousness-Type Double Patenting

Claims 25-34 stand rejected under the doctrine of obviousness-type double patenting as unpatentable over claim 1 of Flenø. According to the record, the Flenø patent and the present application have a common inventor, but are not commonly owned. In deciding this issue, we have considered the arguments made in appellants' Brief and Reply Brief (paper nos. 39 and 41) and in the Examiner's Answer (paper no. 40). We have also considered the prosecution histories of the present application and parent application serial no. 08/067,797 (abandoned); as well as the prosecution history of U.S. Patent 5,536,810 to Flenø.

Claim 1 of Flenø is as follows:

1. An isolated pure culture of a strain of Phaffia rhodozyma which when grown under conditions comprising an oxygen transfer rate of at least 30 mmoles/l/hour on YM medium at 20°- 22° C. for 5 days in 500 ml shake flasks with two baffles containing 50 ml of the medium and subjected to orbital shaking as 150 rpm, produces astaxanthin in an amount of at least 600 µg per g Phaffia rhodozyma dry matter, as determined by HPLC analysis, wherein said strain is Phaffia rhodozyma deposited under accession No. 224-87 CBS, accession No. 225-87 CBS, or accession No. 215-88 CBS, or a mutant thereof which retains the astaxanthin-producing capability.

Claim 25 of the present application, on the other hand, is broadly directed to any mutant Phaffia rhodozyma which produces more than 700 micrograms of astaxanthin per gram of dry yeast when grown on YM medium for six days.

Appellants argue that Flenø "was filed subsequent to the effective filing date of the present application, [but] issued first as a patent" "[b]ecause of [] delays faced by Appellants" (Brief, page 28). Accordingly, appellants submit that, at the very least, "a two-way obviousness analysis would be proper" (id.).

In In re Berg, 140 F.3d 1428, 1432, 46 USPQ2d 1226, 1229 (Fed. Cir. 1998), the court discussed circumstances under which a two-way test of obviousness would be appropriate:

Generally, a "one-way" test has been applied to determine obviousness-type double patenting. Under that test, the examiner asks whether the application claims are obvious over the patent claims. In a recent case, with unusual circumstances, however, this court instead applied a "two-way" test. See Braat, [937 F.2d 589, 592, 19 USPQ2d 1289, 1291-92 (Fed. Cir.1991)]. Under the two-way test, the examiner also asks whether the patent claims are obvious over the application claims. If not, the application claims later may be allowed. Thus, when the two-way test applies, some claims may be allowed that would have been rejected under the one-way test. . . . The essential concern was to prevent rejections for obviousness-type double patenting when the applicants filed first for a basic invention and later for an improvement, but through no fault of the applicants, the PTO decided the applications in reverse order of filing, rejecting the basic application although it would have been allowed if the applications had been decided in the order of their filing.

* * *

. . . Since Braat, many patent applicants facing an obviousness-type double patenting rejection under the one-way test have argued that they actually are entitled to the two-way test. The two-way test, however, is a narrow exception to the general rule of the one-way test. . . . Nevertheless, the notion survives that in certain unusual circumstances, the applicant should receive the benefit of the two-way test. The question then is: when?

According to the court, id., 140 F.3d at 1435, 46 USPQ2d at 1232,

The two-way exception can only apply when the applicant could not avoid separate filings, and even then, only if the PTO controlled the rates of prosecution to cause the later filed species claims to issue before the claims for a genus in an earlier application.

Assuming, for the sake of argument, that the first prong of the test has been met (since the present application and the patent have different inventive entities), the issue becomes whether or not the second prong of the test has been satisfied; that is, whether or not the USPTO controlled the rate of prosecution to cause the patented claim to issue before the broader claims of the present application.

In reviewing the prosecution histories of the relevant applications, we find the following: application serial no. 07/919,986, which was filed on July 27, 1992, and which matured into U.S. Patent no. 5,356,810 (Flenø), is a continuation of application serial no. 07/424,306, which was filed on November 12, 1989. A restriction requirement was mailed in the parent application thirteen months after it was filed (December 4, 1990), and the Flenø applicants responded with an election in approximately two months time (February 8, 1991). A non-final office action was mailed April 15, 1991; a three month extension of time was granted and the office action was responded to on October 18, 1991. A final office action was mailed January 27, 1992 and responded to in approximately two months (April 3, 1992). On August 27, 1992, the application was abandoned in favor of a file-wrapper-continuation (07/919,986). A non-final office action was mailed in the continuing application on May 3, 1993, and responded to within three months (July 27, 1993). A final rejection was mailed on October 18, 1993; a three month extension of time was granted and the office action was responded to on April 13, 1994. A notice of allowance was mailed on April 26, 1994, and the application issued as Patent no. 5,356,810 on October 18, 1994.

The prosecution history of the present application is as follows. The present application is a continuation of serial no. 08/067,797 (filed May 27, 1993), which is a continuation of serial no. 07/837,120, (filed February 14, 1992, now Patent no. 5,356,809), which is a divisional of serial no. 07/399,183 (filed August 23, 1989), now Patent no. 5,182,208), which is a continuation of serial no. 07/385,961 (filed July 28, 1989), which is a continuation-in-part of serial no. 07/229,536 (filed August 8, 1988).

On review of the record, it appears that claims similar to the claims presently on appeal first appeared on May 27, 1993, by way of a preliminary amendment filed in serial no. 08/067,797, the immediate parent of the present application. Thus, although the subject matter on appeal was disclosed at least as early as July 28, 1989, it was not claimed until Flenø's application 07/919,986 (which matured into Patent 5,356,810) was in mid-prosecution. A non-final action was mailed in appellants' application 08/067,797 on September 13, 1993, and appellants responded on December 16, 1993 (having been granted a one month extension of time). On April 7, 1994, the examiner suspended prosecution pending availability of a reference. On February 1, 1995, the examiner mailed a final rejection, citing Patent 5,356,810 to Flenø. On August 15, 1995, 08/067,797 was abandoned for purposes of filing a file wrapper continuation (FWC), i.e., the present application 08/458,019. During prosecution of 08/458,019, appellants were granted extensions of time on at least eight occasions; in addition the application was expressly abandoned on November 13, 1997, in order to reopen prosecution under 37 CFR § 1.129. Appellants' Brief on Appeal and Reply Brief were filed August 23, 2000 and March 28, 2001, respectively.

Inasmuch as the subject matter on appeal was disclosed at least as early as July 28, 1989, but was not claimed until Flenø's application 07/919,986 (which matured into Patent 5,356,810) was in mid-prosecution, we see no evidence that Flenø's claimed subject matter "issued first as a patent" "[b]ecause of the delays faced by Appellants"

(Brief, 28), the nine month suspension of prosecution notwithstanding. We conclude that the second prong of the test has not been satisfied, and a two-way obviousness analysis is not required in this instance.¹

Appellants argue that “even a one-way obviousness analysis fails” because “the amount of astaxanthin produc[ed by] the strains claimed by Flenø [(at least 600 µg per g Phaffia rhodozyma dry matter, when grown on YM medium for 5 days)] cannot properly be said to render the strains of the present claims, each reciting mutant strains producing at least 700 µg of astaxanthin [when grown on YM medium for 6 days], obvious” (Brief, page 28). We disagree. It cannot be denied that the properties of the Phaffia rhodozyma mutants encompassed by both the patented and present claims, at the very least, overlap. That is, present claim 25 encompasses any Phaffia rhodozyma mutant that produces at least 700 µg of astaxanthin when grown on YM medium for six days, while the patented claim encompasses a mutant of Phaffia rhodozyma strain CBS 224-87, 225-87 or 215-88 “which retains the astaxanthin-producing capability” of the parent strain. Merely by way of example, we note that Flenø’s CBS 225-87 produced 706 µg of astaxanthin when grown in YM medium for five days (see column 25, line 66 through column 26, line 25). Indeed, the properties of the patented mutants reasonably appear to be the same as those required of the broadly claimed mutants.

¹ In addition, we note that rather than appeal the examiner’s final rejection of January 23, 1995, appellants chose to refile the parent application of this case and continue prosecution for another five and a half years before filing the present appeal. Compare In re Goodman, 11 F.3d 1046, 1053, 29 USPQ2d 2010, 2016 (Fed. Cir. 1993) (“This court did not require a terminal disclaimer [in Braat] because Braat’s application was held up not by the applicant, but by ‘the rate of progress of the application through the PTO, over which the applicant does not have complete control’ . . . This case requires no ‘two-way’ analysis . . . PTO actions did not dictate the rate of prosecution. Rather, appellant chose to file a continuation and seek early issuance of the narrow species claims. The appellant also chose to forego an immediate appeal to this court on its broader claims when it filed a continuation application”).

As appellants point out, "the determination for obviousness-type double patenting parallels the [analysis] for a 35 U.S.C. § 103 (a) rejection" (Brief, page 30). We would add that an analysis with respect to 35 U.S.C. § 102 is relevant as well (under the theory that anticipation is the ultimate of obviousness, see, e.g., In re Fracalossi, 681 F.2d 792, 794, 215 USPQ 569, 571 (CCPA 1982)). As explained in In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977):

Where . . . the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product Whether the rejection is based on 'inherency' under 35 U.S.C. § 102, on 'prima facie obviousness under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products [footnote omitted].

As discussed above, we note a striking level of correspondence between the properties of the Phaffia rhodozyma claimed by Flenø and those of the presently claimed mutants, and hold that the examiner has set forth a reasonable basis for his assertion that the instant claims are but an obvious variation of the patented claim (Answer, page 38), appellants' arguments notwithstanding.

Appellants further argue that the "growth conditions specifically recited in Flenø claim one cannot be said to be taught or suggested by the present appealed claims" (id., page 29). This argument is not persuasive. First, the claims are directed to organisms capable of producing a certain amount of astaxanthin when grown under specified conditions, not to the methods of growing them. Moreover, as explained above, "[u]nder [the one-way] test, the examiner asks whether the application claims are obvious over the patent claims" (Berg, 140 F.3d at 1432, 46 USPQ2d at 1229 (Fed. Cir. 1998)), not the other way around.

Finally, appellants argue that even though “a terminal disclaimer is not possible because the inventions are not commonly owned” (Brief, page 26), they “would not be recipients of an unjustified or improper timewise extension of the right to exclude,” inasmuch as “a different owner [has already] been granted a right to exclude and . . . an ability to prevent issuance of a patent to the Appellants” (*id.*, page 29). Appellants argue that, “unless the rejection is reversed, they “would not obtain the fruits of their invention” (*id.*, page 30), an outcome “the public policy reasons behind the obviousness-type double patenting rejection would militate against” (*id.*, page 31). Nevertheless, whether two patentably indistinct inventions are owned by the same party, or two different parties,

[t]he rule [against double patenting] . . . operates in the public interest. When a patent issues . . . the public should be able, upon seeing the issued patent, to act on the assumption that the patentee's protection is limited to what he claims and that what is not claimed, in the way of obvious modifications, alternatives, and the like, will be free of protection through any later patents issued to the patentee. The public should also be able to act on the assumption that upon expiration of the patent it will be free to use not only the invention claimed in the patent but also any modifications or variants thereof which would have been obvious to those of ordinary skill in the art at the time the invention was made . . .

In re Zickendraht, 319 F.2d 225, 232, 138 USPQ 22, 27 (CCPA 1963) (Rich, J., concurring). We are not unmindful of appellants' dilemma, but the solution, if any, does not lie in disregarding the public policy reasons behind the doctrine of obviousness-type double patenting. Were we to do so, the public would be excluded from practicing the invention long after it should have passed into the public domain.

The rejection of the claims on the ground of obviousness-type double patenting is affirmed.

For the reasons set forth in the body of this opinion, we have affirmed the rejection of claims 25-34 under the doctrine of obviousness-type double patenting, and reversed the rejections of claims 25-34 under the first paragraph of 35 U.S.C. § 112.

AFFIRMED

Demetra J. Mills
Administrative Patent Judge

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